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August 15, 2003

1631

TO: Examiner Carolyn L. Smith (TC1600)

GROUP: 1631

FAX NUMBER: 703-872-9306

ATTORNEY DOCKET NO.: DEX-0313

SERIAL NO.: 10/074,475

FILED: February 12, 2002

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MESSAGE: Attached please find Amendment Transmittal Letter (in duplicate); response to Office Action dated July 16, 2003; and Certificate of Transmission by Facsimile.

Kathleen A. Tyrrell, Registration No. 38,350

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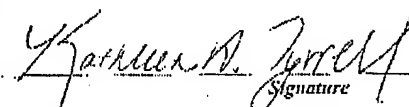
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CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)			Docket No. DEX-0331
Applicant(s): Salceda et al.			
Serial No. 10/074,475	Filing Date February 12, 2002	Examiner Smith, Carolyn L.	Group Art Unit 1631
Invention: Compositions and Methods Relating to Breast Specific Genes and Proteins			
<p>I hereby certify that this <u>Reply to Restriction Requirement</u> (Identify type of correspondence)</p> <p>is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. <u>703-872-9306</u>)</p> <p>on <u>August 15, 2003</u> (Date)</p> <p><u>Kathleen A. Tyrrell</u> (Typed or Printed Name of Person Signing Certificate)</p> <p><u>Kathleen A. Tyrrell</u> (Signature)</p> <p>Note: Each paper must have its own certificate of mailing.</p>			

AMENDMENT TRANSMITTAL LETTER (Large Entity)				Docket No. DEX-0313	
Applicant(s): Saleeda et al.					
Serial No. 10/074,475	Filing Date February 12, 2002	Examiner Smith, Carolyn L.	Group Art Unit 1631		
Invention: Compositions and Methods Relating to Breast Specific Genes and Proteins					
TO THE COMMISSIONER FOR PATENTS:					
Transmitted herewith is an amendment in the above-identified application.					
The fee has been calculated and is transmitted as shown below.					
CLAIMS AS AMENDED					
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	19 -	20 =	0 x	\$18.00	\$0.00
INDEP. CLAIMS	2 -	3 =	0 x	\$84.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$0.00
<input type="checkbox"/> No additional fee is required for amendment. <input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____ <input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed. <input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-1619 <input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16. <input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17.					
 Signature Kathleen A. Tyrrell, Reg. No. 38,350			Dated: August 15, 2003		
Licata & Tyrrell P.C. 66 East Main Street Marlton, New Jersey 08053 Tel: 856-810-1515 Fax: 856-810-1454			<div style="border: 1px solid black; padding: 5px;"> I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. _____ Signature of Person Mailing Correspondence _____ Typed or Printed Name of Person Mailing Correspondence </div>		
CC:					

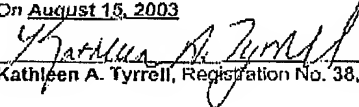
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0313
Inventors: Salceda et al.
Serial No.: 10/074,475
Filing Date: February 12, 2002
Examiner: Smith, Carolyn L.
Group Art Unit: 1631
Title: Compositions and Methods Relating to
Breast Specific Genes and Proteins

Certificate of Facsimile Transmission

I hereby certify that this document is being facsimile
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the date shown below.

On August 15, 2003


Kathleen A. Tyrrell, Registration No. 38,350

Commissioner for Patents
Mail Stop
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed July 16,
2003 setting a one (1) month statutory period for response. Please
enter the following remarks into the record.

Remarks begin on page 2.

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Inventors: Salceda et al.
Serial No.: 10/074,475
Filing Date: February 12, 2002.
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REMARKS

Claims 1-17 are pending in the instant application. Claims 1-17 have been subjected to the following Restriction Requirement:

Group I, claims 1-5 and 7-8, drawn to a nucleic acid, cell, vector, classified in class 536, subclass 23.1, as well as subclass 435, subclasses 325 and 320.1;

Group II, claims 6, 13 and 15, drawn to methods and kits for determining the presence of a breast specific nucleic acid or polypeptide, classified in class 435, subclasses 6 and 7.1, as well as class 422, subclass 61;

Group III, claim 9, drawn to a method for producing a polypeptide, classified in class 435, subclass 69.1;

Group IV, claims 10-11, drawn to a polypeptide, classified in class 530, subclass 350;

Group V, claim 12, drawn to an antibody, classified in class 530, subclass 387.1;

Group VI, claim 14, drawn to a method for diagnosing and monitoring the presence and metastases of breast cancer in a patient, classified in class 436, subclass 64;

Group VII, claim 16, drawn to a method of treating a patient

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with breast cancer, classified in class 514, subclass 2; and

Group VIII, claim 17, drawn to a vaccine, classified in class 514, subclass 2.

The Examiner suggests that the Groups are distinct. In support of this suggestion, the Examiner suggests that Groups [I, II (hybridization species), III, VI (nucleic acid species), and VIII (nucleic acid species)], [IV, VI (protein species), and VII (protein species)], and [II (antibody-binding species), V, and VII] are independent inventions because they are directed to different chemical entity types regarding the critical limitations therein. Further, while the Examiner has acknowledged the relationship of Groups [I, II (hybridization species), III, VI (nucleic acid species), and VIII (nucleic acid species)], [IV, VI (protein species), and VIII (protein species)] and II (antibody-binding species), V and VII] as being related as product and process of use, the Examiner suggests that these Groups are distinct since the products can be used in different processes. In addition, the Examiner suggests that the searching of these different usages is not overlapping and would create an undue search burden if searched together.

Further, the Examiner suggests that each of these Groups reads on patentably distinct sequences.

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In addition, Group II, VI and VIII have been subjected to a species election with respect to determination of a nucleic acid versus a protein.

Applicants respectfully traverse this Restriction Requirement.

At the outset, it is respectfully pointed out that the Examiner's basis for the Groups being distinct because they are independent is flawed since MPEP § 802.01 makes quite clear that inventions cannot be both independent and distinct.

Further, MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of prior art relating to an elected nucleic acid, polypeptide or antibody would also reveal any references teaching uses for the nucleic acid, polypeptide or antibody. Accordingly, Applicants believe that searching of all the claims, at least when limited to elected nucleic acids or polypeptides is overlapping and would not place an undue burden on the Examiner if the Restriction is not made.

Thus, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, reconsideration and withdrawal of this Restriction Requirement is respectfully

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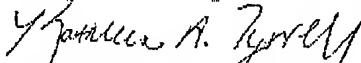
requested.

In addition, with respect to the election of a single sequence, MPEP § 803.04 clearly states that a reasonable number of nucleotide sequences, normally ten sequences, can be claimed in a single application. Accordingly, withdrawal of this sequence election requirement and reconsideration to include a more reasonable number of at least 10 sequences in accordance with MPEP § 803.04 is also respectfully requested.

In an earnest effort to be completely responsive, however, Applicants elect Group 1, claims 1-5 and 7-8, with respect to SEQ ID NO:156 encoding SEQ ID NO: 285, with traverse.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,


Kathleen A. Tyrrell
Reg. No. 38,350

Date: August 15, 2003

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